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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,446	09/01/2004	Antonio Ferrante	P26675CMH:KG	3217

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,446	FERRANTE, ANTONIO	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-62* is/are pending in the application.

4a) Of the above claim(s) *32-41 and 54-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 32-62 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group II (Claims 42-53) in the reply filed on 03/01/06 is acknowledged. The traversal is on the ground(s) that the two Groups are related and a search of both Groups would not present a serious search burden. This is not found persuasive because the two Groups are not so linked through a corresponding special technical feature, the method steps being directed to an *in vivo* assay in Group I and an *in vitro* assay in Group II. Therefore restriction between the Groups according to PCT Rule 13.2 is proper and is upheld.

Claims 32-41 and 54-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/01/06.

Claims 42-53 were examined on their merits.

The requirement is still deemed proper and is therefore made **FINAL.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42, 43, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Costabile *et al.* (2001).

Costabile teaches an assay which measures the activity of an *in vitro* preparation of T-lymphocytes comprising the addition of *n*-3 polyunsaturated fatty acid β-oxa to the T-lymphocytes (Pg. 3981, Column 1, Lines 34-49), measurement of the change in the activity of the T-lymphocytes following addition of the β-oxa (Pg. 3983 Fig. 2A), and comparing the change in activity for the β-oxa treated cells against the change in activity for the known anti-inflammatory *n*-3 polyunsaturated fatty acid docosahexaenoic acid (DHA), the DHA having been measured in the same steps and used to generate a standard against which β-oxa effectiveness is measured (Pg. 3983, Fig. 2A).

Costabile teaches an assay wherein the substance is a biologically active component of oils (fatty acid) (Pg. 3981, Column 1, Lines 15-25).

Costabile teaches an assay wherein the preparation is a preparation of T-lymphocytes and the activity is lympho-proliferation (Pg. 3981, Column 1, Lines 50-65).

Costabile teaches an assay wherein the preparation is a preparation of T-lymphocytes and the activity is production of the cytokines IL-2, Interferon-γ, and TNF-β (Pg. 3981, Column 1, Lines 66-68 and Column 2, Lines 1-8).

Claims 42-44 and 47-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Mak *et al.* (US 2002/0182260 A1).

Mak teaches an assay to assess the anti-inflammatory activity of compounds comprising the measurement of the activity of an *in vitro* preparation of T-lymphocytes (Pg. 22, Column 2, Lines 10-11 and 27-28), addition of Lanolin-related compounds to the T-lymphocytes (Pg. 22, Column 2, Lines 4-10 and 21-27), measuring the change in activity for standard compounds having known anti-inflammatory activity, the effect of those standard compounds having been measured in the same steps as the Lanolin-related compounds, and used to generate a grading system to compare the efficacy of the Lanolin-related compounds Pg. 22, Column 2, Lines 37-53 and Pg. 23, Table 10).

Mak teaches an assay system wherein the substance is animal oil, organic solvent extracts of animal oil, preparation comprising animal oil, and biologically active components of animal oil (Pg. 19, Column 1, 17-40 and Pg. 22, Column 1, Lines 50-53 and Column 2, Lines 1-53, and Pg. 23, Table 10).

Mak teaches an assay system wherein the preparation is a preparation of T-lymphocytes and the activity is proliferation (Pg. 22, Column 1, Lines 50-53 and Column 2, Lines 1-53, and Pg. 23, Table 10).

Mak teaches an assay system wherein the preparation is a preparation of T-lymphocytes and the activity is production of the cytokine IL-2 (Pg. 12, Lines 38-47 and Pg. 22, Column 1, Lines 50-53 and Column 2, Lines 1-53, and Pg. 23, Table 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costabile *et al.* (2001) in view of Ghosh *et al.* (5,431,924).

The teachings of Costabile were discussed above.

Costabile does not teach wherein the substance is selected from animal or plant oils, selected from tea tree, linseed, borage, and evening primrose oils, fish oils, and algal, microbial and fungal oils, or wherein the substance is emu oil or an ethanol extract of emu oil.

Ghosh teaches the use of emu oil as an anti-inflammatory composition (Column 6, Lines 51-54), evening primrose oil (Column 2, Lines 3-6) and fish oils (Column 1, Lines 33-49) and tea tree and Linseed oils (Column 2, Lines 10-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the assay taught by Costabile which measures the activity of an *in vitro* preparation of T-lymphocytes with the use of other polyunsaturated fatty acids from natural sources as taught by Ghosh because the ordinary artisan would have been familiar with the use of isolated natural compounds from natural oils as the basis by which many new compounds can be refined from or synthesized in order to obtain more desirable experimental results. The ordinary artisan would have been motivated to use animal (emu) or plant oils in the method taught by Costabile as a means of control in the experiment involving a novel synthetic polyunsaturated fatty acid.

Indeed, Ghosh discloses the control elements used by Costabile as having known anti-inflammatory activities (Column 1, Lines 46-49). The ordinary artisan would have had a reasonable expectation of success based upon the similarity of the two methods in examining the effects of polyunsaturated fatty acids on t-lymphocyte cell preparations.

Claims 42, 43, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costabile *et al.* (2001) in view of Schmidt *et al.* (1989).

The teachings of Costabile were discussed above.

Costabile does not teach a method wherein the cells are neutrophils and the activity measured is chemotaxis.

Schmidt teaches a method for characterizing the anti-inflammatory activity of fish oil wherein neutrophil chemotaxis is examined (Pg. 55, Column 1, Lines 1-8 and Table 1).

It would have been obvious to one of ordinary skill at the time the invention was made to combine the assay taught by Costabile which measures the activity of an *in vitro* preparation of T-lymphocytes with the method of assessing the anti-inflammatory activity of fish oil on neutrophils as taught by Schmidt because the methods are both drawn toward characterizing the anti-inflammatory activity of natural oil compounds on the various activities of certain types of cell from the immune system. The ordinary artisan would have been motivated to apply the method of Costabile to include an examination of other immune cells and activities in order to obtain a more complete picture of the effects of a compound on the entire immune system. The ordinary artisan would have had a reasonable expectation of success based upon the similarities between the two methods and the success of the methods in determining anti-inflammatory activities separately.

Claims 42, 43, 47-49, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costabile *et al.* (2001) in view of Sethi *et al.* (2002).

The teachings of Costabile were discussed above.

Costabile does not teach a method wherein the cells are neutrophils and the measured activity is adherence to endothelial cells, or wherein the assay steps are repeated using serially reducing amounts of a substance serially diluted in ethanol.

Sethi teaches a method involving the polyunsaturated fatty acid eicosapentaenoic acid (EPA) and its effects on the adherence of neutrophils to endothelial cells (Pg. 1341, Column 1, Lines 14-30 and Pg. 1342, Figs. 1 & 2).

Sethi teaches a method wherein the assay is repeated using serially reducing amounts of EPA which has been serially diluted in ethanol (Pg. 1341, Column 1, Lines 1-13 and Pg. 1342, Fig. 1).

It would have been obvious to one of ordinary skill at the time the invention was made to combine the assay taught by Costabile which measures the activity of an *in vitro* preparation of T-lymphocytes with the method of assessing the anti-inflammatory activity of EPA on neutrophils as taught by Sethi because the methods are both drawn toward characterizing the anti-inflammatory activity of polyunsaturated fatty acids on the various activities of certain types of cell from the immune system. The ordinary artisan would have been motivated to apply the method of Costabile to include an examination of other immune cells and activities in order to obtain a more complete picture of the effects of a compound on the entire immune system. It would have been further obvious to one of skill in the art at the time of the invention that standard experimental procedures for screening compounds require a serial dilution in a delivery vehicle (solvent?) in order to test different concentration ranges in order to determine the most effective dosage.

The ordinary artisan would have had a reasonable expectation of success based upon the similarities between the two methods and the success of the methods in determining anti-inflammatory activities separately.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

03/31/06

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER